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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., ET AL.,
Petitioners,

v.

IVES LABORATORIES, INC.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

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BRIEF FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The Pharmaceutical Manufacturers Association ("PMA") is a voluntary nonprofit association of 149 companies engaged in the discovery, development, manufacture and marketing of prescription drugs, medical devices and diagnostic products. Its member companies have created and introduced, at great expense and scientific effort, most of the prescription drugs on the market today. They differ in this respect from so-called generic drug manufacturers, such as petitioners, who engage in no research and development but concentrate their efforts on the manufacture and sale of generic formulations of drugs developed by others.

At issue in this case is the practice of some generic manufacturers of making their products in the same size, shape and color as the trademarked "pioneer" products of many PMA members. If the Court were generally to uphold the legality of these "look-alikes," consumers would be left with no effective protection against deceit, and the ability of innovative manufacturers to build and

protect a reputation for quality and reliability would be severely impaired, thus distorting competition in the market. PMA therefore files this brief as *amicus curiae* supporting respondent to set forth its views on the broad policy questions implicated by petitioners' claims.[1]

THE ESSENCE OF THE CONTROVERSY

This case challenges the attempts of three manufacturers of generic prescription drugs to bolster their competitive positions by dressing their cyclandelate drug products so as to make them identical in size, shape and color to respondent's original and well-accepted cyclandelate product Cyclospasmol.® The avowed purpose of such imitation (Darby Br. at 11 n.*) is "to equate their products with the market leaders in every way, except for price." This implied representation that "look-alikes" are the same as the originals "in every way" is contrary to fact—certainly as to the source of the product, and in all likelihood as to manufacturing methods, quality control procedures and "inactive" but necessary ingredients that can affect the drug's therapeutic performance. It is deception in the most simple and obvious sense: the consumer does not receive what he is led to believe he is getting.

In every modern case of this kind, including this one, the courts have held that the manufacture and sale of "look-alike" drugs is unlawful. But neither this case nor any of its predecessors has had the purpose or effect of preventing fair and open competition between generic and trademarked prescription drug products. Rather, these cases all have been concerned with consumer deception. The courts have acted to protect the consumer's right to know whether the medication he is receiving from his pharmacist is the trademarked product prescribed, or a generic substitute.

As the evidence in these cases bears out, the method by which prescription drugs are sold makes it inevitable

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[1] Pursuant to the Court's Rule 36.2, the written consents of all parties to this case are being filed with the Clerk herewith.

that "look-alike" drugs will be used by some pharmacists as an instrument of consumer deception. Although all drug manufacturers are required by law to distribute their products to retailers in containers that clearly identify their source, the drugs themselves are rarely dispensed to consumers in their original packages. Instead, pharmacists usually remove the products from the original packages and dispense them in their own containers, affixed to which are labels typed by the pharmacists themselves. Thus, where substitution of generics is permitted, a pharmacist can easily dispense a "look-alike" and label it with the original's trademark, with confidence that the patient will not know the difference. Even worse, a pharmacist can practice deception by using a "look-alike" generic to fill a prescription that specifically requires the trademarked product.

As will be shown below, there is a strong economic incentive for pharmacists to engage in illegal substitution and mislabeling. Pharmacies' profit margins on generic drugs are often higher than on the trademarked original products, even when they sell the generics at prices below those generally charged for the trademarked drugs. And, of course, a pharmacist bent on deception can easily pass off a "look-alike" as the trademarked product at a price that only the well-accepted original could truthfully command.

Although petitioners and their *amicus* supporters have suggested that it is traditional for generic drugs to be manufactured to resemble their brand-name counterparts, the fact is that the problem presented by this case is relatively new. Before 1970, concern that generic drugs might be inferior to brand-name products had led most states to enact "anti-substitution" laws prohibiting pharmacists from dispensing generic substitutes when physicians had prescribed drugs by brand name.[2]

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[2] *See* Note, *Consumer Protection and Generic Drugs: The Generic Drug Substitution Laws*, 67 Ky. L.J. 384, 389-90 (1978-79); Grabowski & Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, 43 Law & Contemp. Prob. 43, 49 (1979).

To the extent generics were marketed in "look-alike" form to facilitate substitution, they were intentional instruments of illegality and fraud.[3] Not until the 1970's did the states begin to replace these anti-substitution laws with statutes that permit or require substitution of generic for trademarked drugs unless expressly prohibited by the physician. It was the enactment of these new substitution laws that first created a large lawful market for generic drugs,[4] and thus made the "look-alike" issue one of widespread concern.

The new state substitution laws, however, are in no way intended to encourage or even condone consumer deception. To the contrary, these laws generally contemplate that patients will be informed of any substitution, and they all also permit physicians to write prescriptions so as to preclude substitution of a generic for the trademarked product. Their purpose is to provide consumers with a choice, not to facilitate fraud.

The "look-alike" manufacturers claim that their products are in all respects medically equivalent to their trademarked original counterparts. But, as we shall show, this is not always so. It is therefore prudent, and surely not irrational, for physicians or patients to insist upon a particular brand whose therapeutic and other relevant characteristics are well known to them. But regardless of this, the right of the consumer to choose, and to be accu-

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[3] When "look-alike" marketing was encountered, "pioneer" manufacturers sought and generally obtained relief under state unfair competition law against "look-alike" imitators of their product sizes, shapes and colors. *See, e.g., Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190 (9th Cir. 1953); *Smith Kline & French Labs. v. Broder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959); *Smith Kline & French Labs. v. Midwest Chem. Dev. Corp.*, 96 F. Supp. 797 (N.D. Ohio 1951); *Smith Kline & French Labs. v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976 (S.D.N.Y. 1950), which petitioners conveniently all but ignore.

[4] In 1966, for instance, only 6.4% of new prescriptions were written generically. *Drug Product Selection: Staff Report to the Federal Trade Commission* 45 (1979).

rately informed, is at the heart of the competitive system. It is this principle that the Second Circuit in this case, and other courts in similar cases, have sought to preserve.

SUMMARY OF ARGUMENT

I.

This case does not present the "look-alike" issue in a form that would enable the Court fully to resolve it. Every other recent case on this subject has held the "look-alike" practice to be unlawful under Section 43(a) of the Lanham Act, but the Second Circuit in this case relied solely on Section 32 of the Act to reach the same result. Thus, regardless of whether this Court affirms or reverses the judgment below, the Section 43(a) issue would remain unresolved. This case is therefore not a suitable vehicle for settling the "look-alike" issue, and accordingly the writ should be dismissed as improvidently granted.

II.

The practice of manufacturing and marketing generic prescription drugs in the same size, shape and color as the original trademarked products they seek to supplant serves no purpose other than consumer deception.

A. Petitioners' efforts to justify "look-alikes" on health-related grounds will not withstand analysis. Their arguments have been rejected by every court that has considered them (except the district court in this case), as well as by the Food and Drug Administration.

First, petitioners argue that a patient who receives a generic drug that differs in appearance from the trademarked product to which he is accustomed will experience "anxiety" about whether the generic is therapeutically equivalent. But generics may only be substituted for the trademarked drug prescribed if the physician and the patient have agreed to accept such substitution, which should allay any concern about the generic's outward appearance. The "anxiety" feared by petitioners is the

reluctance of some patients—not necessarily unfounded—to accept generic substitutes for their accustomed trademarked products, an "anxiety" petitioners seek to avoid by camouflaging the differences between the two.

Second, petitioners argue that patients sometimes commingle several medications, and rely on the color to differentiate one from another. But even if some patients use this risky method of identifying different drugs, a generic can be as easily distinguished from other medicines when it has its own distinctive color.

Third, petitioners contend that the color of a drug product can assist physicians in determining what drug was taken by an overdose victim. In fact, however, physicians cannot and do not rely on color for this purpose, as unrelated drugs often look alike.

Although the district court purported to find as a "fact" that the medical justifications offered by petitioners for "look-alikes" were valid, this is not really an issue of fact to be decided again and again on the record of each case. There must ultimately be one rule as to whether "look-alike" generic drugs serve any legitimate purpose. The rule should be, as the lower courts have consistently held, that "look-alikes" serve no purpose but consumer deception.

B. Nor is there merit in petitioners' argument that only "look-alike" generics can compete effectively with brand-name products. There are many successful generic drugs on the market that do not imitate the appearance of the original trademarked products they seek to supplant, and generic manufacturers as a class are thriving.

C. For public health reasons, consumers must be able readily to recognize generic substitutes. In too many instances, generics differ from the trademarked originals in important pharmacologic respects. The unlawful substitution and mislabeling made practicable by "look-alike" appearance leads consumers unknowingly to accept products that can in some cases cause serious injury or death.

III.

The practice of marketing "look-alikes" is inconsistent with the consumer-choice and pro-competitive policies of state substitution laws. These laws permit the substitution of generic for prescribed trademarked products only with the consent of the physician and the patient. "Look-alike" drugs enable the pharmacist to deceive the patient, and thus undermine this fundamental right of consumer free choice. Moreover, if petitioners cannot offer products so well suited for deception they will have to find other competitive weapons—presumably, price. Allowing "free riders" on the pioneer manufacturers' reputations is also likely to discourage innovation, and thus impair competition and economic efficiency. Finally, "look-alike" appearance makes it possible for manufacturers of defective drugs to shift liability for the harm caused by their products, thus further distorting competition.

IV.

The court of appeals correctly held that petitioners were guilty of contributory trademark infringement under Section 32 of the Lanham Act.

A. Petitioners claim that they should not be held liable for the infringements committed by pharmacists, because they neither intended nor had reason to anticipate that their products would be used in that fashion. The evidence in this record, however, as well as the evidence in numerous similar cases, establishes that mislabeling and illegal substitution are widespread and pervasive. Furthermore, as petitioners also are aware, there is often a strong economic incentive for pharmacists to engage in these practices, because of the higher profits available to them on sales of generics. Thus, petitioners had every reason to anticipate infringement.

B. The decision below is fully consistent with this Court's decisions in *Sears* and *Compco*. Those cases merely held that state unfair competition laws could not be used to prevent copying of the configuration of

products that were not protected by patents. In this case, we are concerned with federal, not state, law; the issue is trademark infringement and deception, not product simulation as such; and the practice involved is copying of trade dress, not the configuration of the product itself.

ARGUMENT

I. BECAUSE THIS CASE IS NOT A SUITABLE VEHICLE FOR RESOLVING THE "LOOK-ALIKE" CONTROVERSY, THE COURT SHOULD DISMISS THE WRIT AS IMPROVIDENTLY GRANTED.

Although the lawfulness of "look-alike" generic drugs is clearly an important issue, this case does not present that issue in a form that would enable the Court fully to resolve it. Accordingly, PMA respectfully suggests that the Court proceed no further with this case, but instead dismiss the writ of certiorari as improvidently granted.

In every modern case in which the manufacture and sale of "look-alike" drugs have been challenged, including this one, the plaintiff's principal claim has been that the practice constitutes false designation of origin and false representation in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and unfair competition under state law. In some cases, as here, plaintiffs have also contended that "look-alike" marketing constitutes contributory trademark infringement under Section 32 of the Act, 15 U.S.C. § 1114. In all cases prior to the present one, however, the courts have upheld the plaintiffs' claims under Section 43(a) or equivalent state law principles. In this case, for the first time, the court pretermitted the Section 43(a) issue, and relied entirely on Section 32 to grant relief.

Because the Second Circuit's decision was so limited in scope, this case is not a suitable vehicle for this Court definitively to settle the lawfulness of "look-alike" drugs. Respondent's Section 43(a) claims are still unresolved and will remain so regardless of this Court's ruling on

Section 32. Yet, as the United States notes in its *amicus* brief (at 14-15), "it is that provision, rather than Section 32, which is at the heart of the present controversy." A decision by this Court affirming the Second Circuit will not necessarily control future cases, which, because of differing facts, may turn primarily or wholly on Section 43(a). A decision reversing the Second Circuit, on the other hand, would require a remand for consideration of the Section 43(a) issue, on which the court of appeals has yet to pass [5] and which has not been fully briefed by any party.

We therefore suggest that certiorari was improvidently granted, and that the writ should be dismissed. If the Court reaches the merits of this case, however, for the reasons that follow, it should affirm the decision below.

II. IMITATION OF THE SIZE, SHAPE AND COLOR OF A PRESCRIPTION DRUG PRODUCT SERVES NO PURPOSE BUT DECEPTION OF PATIENTS.

Petitioners and their *amicus* supporters would have the Court believe that original trademarked drugs and their generic imitations are one and the same, in all respects fungible and interchangeable, and that it is a matter of indifference to patients whether they are sold one or the other. This is not so. Generic drugs, while usually containing the same active ingredients as their brand-name counterparts, are made by different manufacturers (often having different reputations for reliability and integrity), are manufactured by different methods using different quality control procedures, and contain different "inactive" but pharmaceutically necessary ingredients. Some generic products, in fact, have been found to have important differences in their pharmacologic effects on patients. See pp. 17-20 *infra*. But

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[5] "We do not ordinarily address for the first time in this Court an issue which the Court of Appeals has not addressed * * *." *J. Truett Payne Co. v. Chrysler Motors Corp.*, 101 S. Ct. 1923, 1930 (1981).

even where no such differences have been directly demonstrated, many physicians and consumers insist upon the trademarked original product, and are unwilling to take chances with generic imitations.[6]

Pharmacists often, however, make a larger profit on generic drugs. See p. 26 *infra*. Thus, even when prescriptions specifically require trademarked products, there is an economic incentive to substitute generic products. The fact that generic cyclandelate is sold in capsules identical in size, shape and color to Cyclospasmol ® makes it easy—and undoubtedly tempting—for a pharmacist to fill a prescription that calls specifically for Cyclospasmol ® with a "look-alike," without fear of detection. All he need do is to type Cyclospasmol ® on the label.

Even if a pharmacist is unwilling to engage in such blatant misconduct, moreover, few consumers would be alerted to a substitution—legal or illegal—by a label that says "generic Cyclospasmol," much less "Cyclospasmol (gen)" or the like:

> Whether adding the letters "Gen" or the word "generic" actually tells the consumer that he or she is being switched * * * is questionable—absent explicit information from the pharmacist. Consumers are unlikely to learn of the change in medication from what is probably, for them, an obscure word or phrase.

Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, Inc., 211 U.S.P.Q. 1163, 1181 (D.N.J. 1980). If a patient has been taking a specific trademarked product, has a prescription naming that product, and receives a

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[6] The Food and Drug Administration has acknowledged that among prescription drug consumers, especially the elderly, "doubts * * * may exist regarding the safety, effectiveness, and economic advantage" of generics. 45 Fed. Reg. 72582 (Oct. 31, 1980). Consumer preference for a particular brand is especially common in the case of drugs that are used for extended periods, such as Cyclospasmol.® Patients who have had good results with a particular product are frequently unwilling to experiment with generic substitutes.

pharmacist-prepared vial of capsules that look identical to that product, he will naturally assume that he has received that product.

This is why so many cases under Section 43(a) of the Lanham Act have held that the size, shape and color of the drugs involved have a "secondary meaning" identifying their source. Those courts have recognized that consumers rely on appearance to identify trademarked prescription drug products to which they are accustomed.[7]

The evidence in this case, involving 34 separate instances of trademark infringement,[8] illustrates how "look-alikes" facilitate consumer deception. Petitioners' disclaimers of intent to deceive, and purported justifications for marketing "look-alikes," cannot withstand examination.

A. The Purported Medical Justifications for "Look-Alikes" Are Invalid.

Petitioners seek to justify "look-alike" drugs on a variety of health-related grounds. These same arguments have been rejected by every court that has considered

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[7] *SK&F, Co. v. Premo Pharmaceutical Labs., Inc.*, 625 F.2d 1055, 1064 (3d Cir. 1980); *A.H. Robins Co. v. Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1020 (E.D. Mo. 1980) (in which petitioner Inwood was a defendant); *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1178 (in which petitioner Premo was a defendant); *Smith Kline & French Labs. v. Midwest Chem. Dev. Corp.*, 96 F. Supp. 797, 798-99 (N.D. Ohio 1951); *Smith Kline & French Labs. v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976, 977 (S.D.N.Y. 1950).

[8] In 15 cases, pharmacists used generic cyclandelate to fill prescriptions specifically requiring Cyclospasmol.® Pet. App. 52a & n.17. (Twelve of these were labeled with Ives' trademark alone, *id.*; a 13th was labeled "Cyclospasmol 400 mg Bolar Equivalent," Pl. Ex. 98, R. 247-49.) Ten "substitution permissible" prescriptions (29% of the relevant shoppings) were filled with generic cyclandelate mislabeled as Cyclospasmol.® Pl. Exs. 82A, E, S, T, BB, DDD, R. 392-93; 82 HHH, OOO, SSS, TTT, R. 85, 377. Finally, nine vials of generic cyclandelate, out of a total of 17 that were examined while in the possession of patients, were mislabeled as Cyclospasmol.® Pl. Exs. 28-30, R. 109a, 111a-12a, 114a; 33-38, R. 66b, 70b, 78b, 82b.

them (except the district court in this case),[9] as well as by the Food and Drug Administration.[10] They deserve the same fate here.

First, petitioners argue that if a patient who is accustomed to a trademarked product is given a generic substitute having a different appearance, he will be apprehensive about the equivalence of the generic, and that this "anxiety" may impair both the acceptability and even the effectiveness of the drug.[11] In effect, this is an argument that deception is good for the patient, that it is better for him *not* to know that the drug he is receiving is not in all respects identical to the trademarked product prescribed.

As the United States points out in its *amicus* brief, this is the "highly paternalistic approach" repudiated by this Court in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). In addition, it flies in the face of state substitution laws, which generally contemplate that the patient be informed when a generic is substituted for a trademarked product prescribed by his physician. See pp. 20-21 *infra*. FDA, too, "recognizes the need for consumers to be in-

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[9] *See SK&F v. Premo, supra*, 625 F.2d at 1060-61; *Biocraft Labs., Inc. v. Merck & Co.*, No. 77-693 (D.N.J. Oct. 2, 1980), slip op. at 12; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171-72; *Hoffmann-La Roche, Inc. v. Premo Pharmaceutical Labs., Inc.*, 210 U.S.P.Q. 374, 385 (D.N.J. 1980).

[10] FDA has denied a petition by *amicus* the National Association of Pharmaceutical Manufacturers ("NAPM"), based on the same arguments advanced here, to impose a general requirement that all formulations of a prescription drug—generic and trademarked—be manufactured in the same size, shape and color. FDA's letter denying the NAPM petition is reproduced at pp. 1a-2a *infra*.

[11] There is no suggestion in this record that the colors selected by Ives for its Cyclospasmol ® capsules were chosen on any therapeutic or psychological basis. They were selected arbitrarily, solely to give these products a distinctive trade dress. Thus, the argument of *amicus* NAPM (Br. at 4, 5, 8) that the colors of some drugs are chosen for their psychological effects has no bearing whatsoever on this case.

formed when drug substitution occurs in order to prevent them from receiving another product without their knowledge." 45 Fed. Reg. 72582, 72596 (Oct. 31, 1980).[12]

A properly informed patient who accepts a generic substitute is unlikely to feel any "anxiety" about differences in appearance between the generic and the brand-name drug; he will understand that they are made by different manufacturers. *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171. If instead he insists on receiving "the real thing," the trademarked product he has long known and used, that is his right, whether petitioners want him to exercise that choice or not. "[T]he public is entitled to get what it chooses * * *." *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 78 (1934).[13]

If an informed patient experiences any "anxiety" about a generic with a different appearance, it is not because he is apprehensive about the appearance of the drug *per se*, but because he prefers the security of the brand name's history and reputation. Thus, the lower courts[14] have rejected the contention that the avoidance of patient anxiety justifies "look-alike" marketing.[15]

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[12] Petitioners suggest that elderly patients may not be capable of understanding or making the necessary choices. But the elderly no less than any other consumers are entitled to full disclosure when a generic has been substituted. If a patient, young or old, has some mental impairment, the physician will know how to deal with the problem.

[13] *Cf. General Motors Corp.*, 93 F.T.C. 860 (1979) (consent order to cease and desist, on allegations that Chevrolet engines were substituted in Buick, Oldsmobile and Pontiac cars without informing purchaser).

[14] *SK&F v. Premo, supra*, 625 F.2d at 1061; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171; *Hoffmann-La Roche v. Premo, supra*, 210 U.S.P.Q. at 385.

[15] Although petitioners claim that some hospitals demand generics in "look-alike" form, the record in this case contains next to no evidence that this is so. But insofar as some hospitals might insist on "look-alikes," they too can only be attempting to stifle a legitimate form of consumer "anxiety"—the lack of confidence that

Second, petitioners contend that patients who are taking more than one drug may sometimes commingle them and rely on appearance to differentiate one from another. But even if some patients do use this risky method to distinguish their medicines, the differentiation can as readily be made with non-"look-alike" drugs, as long as they differ from others the patient is taking. *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171-72.[16]

Third, petitioners assert that "look-alike" appearance assists emergency room physicians in identifying the drugs taken by overdose victims. But so many unrelated drugs look so similar that doctors cannot and would not rely on color and form alone to identify the drug taken. *E.g.*, *SK&F v. Premo, supra*, 625 F.2d at 1060.

Petitioners contend that the issue whether any legitimate purpose is served by making their generic cyclandelate products look like Ives' Cyclospasmol® is an issue of fact, and that the district court's rulings on that issue in their favor are not "clearly erroneous" and must therefore be upheld. We submit, however, that this is not an issue of fact, to be decided

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some patients have in generic substitutes of unfamiliar or dubious provenance. By dispensing "look-alike" drugs, these hospitals hope to avoid the questions that might be asked, or the objections that might be raised, by patients who are alerted to a substitution. Deception on the part of hospitals, even if benignly motivated, is no more acceptable than deception by retail pharmacies. Hospitalized patients should not be denied the protection provided by the Lanham Act against deception, as the United States in its *amicus* brief (at 32) seemingly would do.

[16] If a physician is concerned that renewal prescriptions will be filled with generics of different colors and that his patient is not alert enough to remember the color of the current prescription, he can prescribe a particular generic by name. Some generic manufacturers—including prominent members of petitioners' *amicus* supporter NAPM—directly advertise to physicians, urging that "[d]octors should specify," *e.g.*, "Biocraft * * * high quality generic drugs." 305 N. Engl. J. Med. xxxvi (Dec. 3, 1981).

anew—and perhaps inconsistently—in each case.[17] The same issue arises in every "look-alike" case, and the arguments presented do not vary according to the particular drug at issue.[18] It would be irrational to hold that the result in each case depends upon how a particular fact-finder happens to evaluate the particular record made on these matters of general applicability. There must ultimately be one rule as to whether "look-alike" generic drugs serve any legitimate purpose.[19] In framing that rule, the Court must be free to examine not only this record but other cases, as well as other sources of information, to reach a judgment on the issue as a matter of law. Every court to pass upon the question, except the district court in this case, has held that "look-alike" marketing serves no legitimate purpose. This Court can and should reach the same conclusion.

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[17] The district court in this case held that "look-alike" appearance was "functional"—that it was justified by purposes other than deception. "Functionality," however, is not a fact but a legal characterization, to which the "clearly erroneous" standard does not apply. This Court held in *United States v. Singer Mfg. Co.*, 374 U.S. 174, 193 (1963), that what acts constitute "conspiracy" under the Sherman Act is a matter of law; the district court's "finding" of no conspiracy was overturned because, on the facts as found, this Court held that a conspiracy existed. Here, even if the district court's conclusions about patient "anxiety," commingling of drugs and emergency room identification are deemed to be factual findings, under the Lanham Act these "facts" are insufficient as a matter of law to justify "look-alike" marketing, under the "functionality" rubric or any other. The policy of the Lanham Act against consumer deception outweighs any of these supposed advantages.

[18] The same witnesses testify in these cases for the "look-alike" manufacturers. Dr. Jerry Bloom, for example, testified both in this case and in *Boehringer v. Pharmadyne, supra*.

[19] A different issue might be presented if the color of a medication were chosen because of some unique psychological meaning, or because it was the natural color of the main ingredient—*e.g.*, brown for chocolate or white for milk. But that is not the situation here.

B. Generic Drugs Can Compete Successfully in Non-"Look-Alike" Form.

Petitioners' claim that only "look-alike" drugs can compete effectively with trademarked originals is equally without merit. In fact, as found in several litigated cases, many generics that are manufactured in distinctive form do compete successfully.[20]

Any competitive advantage for "look-alikes," moreover, could only result from the deception of patients. Identity of appearance facilitates sales of generic drugs only to consumers who want the original trademarked product or one identical in all respects, and who are deceived by the appearance of the generic. As the Third Circuit acidly observed, "[p]robably [the "look-alike" manufacturer] could compete better still if it could appropriate the same trade name." *SK&F v. Premo, supra*, 625 F.2d at 1067.[21]

Contrary to the impression left by petitioners, generic manufacturers are no mere upstarts struggling to survive and likely to perish without special privileges. In 1978, sales of generics, at manufacturers' prices, amounted to $1.4 billion or 20 percent of the prescription drug market. By 1985, generic sales are expected to triple.[22] Petitioners

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[20] *See SK&F v. Premo, supra*, 625 F.2d at 1060 n.3, 1064; *Biocraft v. Merck, supra*, slip op. at 12; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1173. The record in *SK&F v. Premo*, Appendix at 183-85, shows that SK&F itself makes 16 generic products in non-"look-alike" form and that, despite a relative lack of promotion, these products compete successfully.

[21] The Generic Pharmaceutical Manufacturers Association, as *amicus curiae*, claims (Br. at 10-11, 26-27) that "look-alike" marketing is competitively necessary because generic manufacturers do not promote their products to physicians and pharmacists as extensively as brand-name manufacturers do. If petitioners find themselves at a disadvantage because they do not sufficiently promote their products, their recourse is to promote more vigorously or find some competitively effective alternative, not to deceive patients.

[22] SRI International, *A U.S. Generics Breakthrough?* 19 (1980).

themselves are among the leaders in generic sales.[23] They need no special dispensation from unfair competition laws to compete successfully.

C. "Look-Alike" Generic Drug Products May Endanger Public Health.

The consumer deception promoted by "look-alikes" can affect more than matters of consumer choice and economic interest. Previous cases have established that generic drugs do not always meet the standards of the trademarked products they imitate.[24] In *SK&F v. Premo*, *supra*, petitioner Premo's "look-alike" version of Dyazide ® released so much more active ingredient into the bloodstream that a toxic accumulation of potassium could result. 625 F.2d at 1061 & n.4.[25]

In *United States v. Premo Pharmaceutical Laboratories, Inc.*, 511 F. Supp. 958, 994-99 (D.N.J. 1981), the district court found similar potentially serious bioavailability differences in Premo's generic versions of five other drugs:

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[23] 184 Am. Druggist 3, 52-70 (1981). Petitioner Rugby, for example, leads all other companies in supplying hydrochlorothiazide for prescriptions that permit substitution. *Id.* at 60.

[24] A "look-alike" may not even contain precisely the same active ingredients as the copied product. *Hoechst AG v. Generix Drug Corp.*, No. 80-6251-Civ.-Jag. (S.D. Fla.), *consent judgment entered*, July 30, 1980; *Eli Lilly & Co. v. Rugby Labs., Inc.*, No. 77 Civ. 27 (E.D.N.Y.), *dismissed pursuant to settlement*, Jan. 16, 1978; *cf. Pennwalt Corp. v. Zenith Labs., Inc.*, 472 F. Supp. 413 (E.D. Mich. 1979), *appeal dismissed*, 615 F.2d 1362 (6th Cir. 1980) (different amount).

[25] Generic products do not contain the same inactive ingredients as the products they imitate, nor are they made by the same processes or subject to the same quality control procedures. This may cause differences in "bioavailability"—the rate at which active ingredients are released into the body—which in turn may mean differences in therapeutic effect. *See United States v. Premo Pharmaceutical Labs., Inc.*, 511 F. Supp. 958, 962-65 (D.N.J. 1981).

Drug [26]	Condition Treated	Potential Adverse Consequences of Varying Bioavailability
trifluoperazine	psychosis	involuntary movements causing permanent injury
allopurinol	gout	urinary failure
doxylamine succinate	nausea due to pregnancy	dizziness, headaches, drowsiness
hydroxyzine pamoate/ hydroxyzine hydrochloride	emotional distress, psychomotor agitation	drowsiness, tremors, convulsive episodes
chlorthalidone	hypertension and edema	cardiac toxicity, leading to death

In *Pharmadyne Laboratories, Inc. v. Kennedy*, 596 F.2d 568 (3d Cir. 1979), the court relied on evidence that Pharmadyne's generic furosemide, as formulated, was "'very likely * * * ineffective'" (at 572 n.8); this, FDA told the court, "could result in serious complications or even death." [27]

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[26] Another inequivalent Premo drug is insulase, used to reduce blood sugar in diabetes patients. The record in *Premo Pharmaceutical Labs., Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980), Appendix at 100, contains evidence that Premo's form of that drug simply did not work.

[27] *Pharmadyne* Appendix at 540a. In a press release issued March 30, 1979, FDA warned of the grave harm that generic furosemides then marketed could cause, and reported four serious incidents. An Ohio pharmacist has been indicted for manslaughter for illegally—and fatally—substituting generic furosemide on a prescription specifying Lasix,® the original brand of the drug. *Ohio v. Cochran*, Cr. No. 81-09-1085 (C.P. Summit County), *indictment returned*, Sept. 11, 1981.

The scientific literature also is replete with evidence that many generics differ in bioavailability from the trademarked products they imitate and that these differences often affect safety or effectiveness. *E.g.*, Office of Technology Assessment, U.S. Congress, *Drug Bioequivalence* 11-14 (1974); D. Chodos & A. DiSanto, *Basics of Bioavailability* (Upjohn Co., 1974); Rubinstein & Eastwood, *The Effect of Lubricant Type and Concentration on the Bioavailability of Furosemide from 40 Mg. Tablets*, 30 J. Pharm. & Pharmacol. 12 (Supp. 1978); DeSante *et al.*, *Generic Propoxyphene:*

Regulation by FDA cannot be relied upon to keep inequivalent generics from the market. All too often, generic products are marketed with no advance FDA review and approval whatsoever, despite the agency's insistence that in most instances to do so is unlawful. *See Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980).[28] The "look-alike" cyclandelate products of petitioners in this very case were placed on the market without any prior FDA review; their legal status under the Federal Food, Drug, and Cosmetic Act is at best unclear.[29]

Need for Clinical Bioavailability Evaluation, 66 J. Pharm. Sci. 1713 (1977); Kramer *et al.*, *Digoxin Bioavailability: Evaluation of a Generic Tablet and Proposed FDA Guidelines*, 66 J. Pharm. Sci. 1720 (1977); Azarnoff & Huffman, *Therapeutic Implications of Bioavailability*, 16 Ann. Rev. Pharm. & Tox. 53 (1976).

[28] *But see United States v. Generix Drug Corp.*, 654 F.2d 1114 (5th Cir. 1981), *petition for cert. filed*, No. 81-1222 (Dec. 30, 1981). Under the Fifth Circuit's ruling, generic drugs can be marketed solely on the *ex parte* determinations of their manufacturers that FDA pre-market review is legally unnecessary and that, as formulated, the unreviewed generic products are in fact safe and effective.

Whatever the legal requirement, moreover, FDA can only proceed by after-the-fact identification and seizure of unsafe or ineffective products where no pre-market approval was sought. And present law not only fails to require, but expressly forbids drug manufacturers to label or advertise their products as approved by FDA. Federal Food, Drug, and Cosmetic Act, § 301(l), as amended, 21 U.S.C. § 331(l). Pharmacists may thus be unaware that the generics they dispense have no FDA approval, and if the unapproved generic is a "look-alike," neither the patient nor the physician will be alerted to the possibility that an unapproved product has been substituted.

[29] *See* Pet. App. 15a. For unapproved generic versions of products—like Cyclospasmol ®—reviewed and approved for safety prior to 1962, but whose effectiveness is still under review pursuant to the Drug Amendments of 1962 (76 Stat. 780), FDA declines to enforce the pre-market approval requirements of the Food, Drug, and Cosmetic Act (§ 505, as amended, 21 U.S.C. § 355) pending completition of the effectiveness review. *See* 40 Fed. Reg. 26142, 26149 (June 20, 1975); FDA Compliance Policy Guide 7132c.08, at 3-4 (Oct. 6, 1976).

Moreover, even FDA approval for marketing does not ensure therapeutic equivalence. "Many" generics that have received the requisite FDA pre-market review and approval are not considered by the agency to be therapeutically equivalent to the pioneer product (or to each other), because of unresolved actual or potential bioavailability problems. 45 Fed. Reg. 72582, 72590-91 (Oct. 31, 1980). Thus, many physicians and consumers understandably insist upon established original products.[30]

III. "LOOK-ALIKE" MARKETING FRUSTRATES THE CONSUMER-CHOICE AND PRO-COMPETITIVE POLICIES OF STATE SUBSTITUTION LAWS.

Although almost all states now permit generic substitution, no state condones—much less encourages—deception of consumers. To the contrary, state laws generally require that patients be informed of any substitution, and,

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[30] It is perfectly reasonable for physicians or consumers to insist on the trademarked products to which they are accustomed even when the state in which they live has judged generic formulations to be therapeutically equivalent. In many instances, other states will have reached the opposite conclusion. Some states, for example, compile "negative formularies," which list generic drugs that may not be equivalent to the brand-name products and that, therefore, the pharmacist may not substitute. Drugs on the negative formularies of some states are not on others. In Arkansas, diphenylhydantoin is on the negative formulary; in Iowa, it is not. Iowa forbids substitution of methaqualone; Missouri allows it, provided the generic is made by a particular company. *See* Arkansas Nonequivalent Drug Product List (n.d.); Iowa Nonequivalent Drug List (Oct. 1981); Missouri Newly Revised Generic Drug Negative Formulary (Oct. 15, 1980).

Other states have "positive formularies"—lists of generic drugs that may be substituted for prescribed trademarked products. Many professionals do not believe that all of the drugs listed on such formularies are as good as the trademarked products. Almost 40% of Wisconsin physicians surveyed do not consider all formulary drugs therapeutically equivalent to the imitated drugs; 35% were undecided; and only about 25% were persuaded that all formulary drugs were equivalent. 48 Wisc. Pharm. 134, 135 (April 1979). If many physicians do not fully trust generics, patients are also entitled to their doubts.

either explicitly or implicitly, give patients the right to refuse the substitute.

The New York statute in this case directs a physician writing a "substitution permissible" prescription that names a trademarked product to inform his patient that a generic drug will be substituted. The patient, if he wishes, can insist on a prescription requiring the trademarked product. *Pharmaceutical Society of the State of New York v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978). The pharmacist is additionally required "to identify the manufacturer of the generic drug substitute for the consumer." *Id.* at 958 n.6.[31]

Freedom of choice is thus a fundamental goal of state substitution laws. "Look-alike" marketing, "instead of advancing that goal, may thwart it." *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, Inc.*, 211 U.S.P.Q. 1163, 1173 (D.N.J. 1980).

Insofar as the states aim to reduce drug costs, the decision of the Second Circuit here is consistent with that purpose. *First*, if generic manufacturers and distributors can no longer market products on the basis of their capacity to deceive, they will have to compete more vigorously as to price.[32] *Second*, "look-alike" manufacturers essentially seek a "free ride" on the efforts and reputation of the brand-name manufacturers who created the market in which they compete. "Look-alikes" deceptively divert the legitimate sales of the brand-name innovators to their lesser-known competitors. Consumers believe they are purchasing one product, when in fact they are pur-

[31] Other states similarly protect the patient's right to refuse a generic product. *See, e.g.*, N.J. Stat. Ann. 24:6E-7 *et seq.* (West Supp. 1981-82). The FTC's Model Drug Product Selection Act, § 2(d), also makes this right explicit. *Drug Product Selection: Staff Report to the Federal Trade Commission* 279 (1979).

[32] Petitioners Darby *et al.* suggest (Br. at 11 n.*) that prices are higher in markets characterized by product "differentiation." This confuses the "differentiation" familiar in economic theory—promotion of products as having distinctively desirable attributes—with "differentiation" of trade dress aimed at preventing deception.

chasing another.[33] This diversion of sales by deception not only constitutes classic "unfair competition," [34] but reduces the economic incentive for discovery and development by innovative manufacturers, in an industry where such incentives may already be insufficient. *See Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 222 (1980).[35] Protection against "free riders" promotes innovation and thus helps, not hinders, competition and economic efficiency. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974).[36]

Finally, "look-alike" marketing allows companies making defective products to shift liability to innocent trademarked competitors, thus shifting part of their costs and artificially enhancing their competitive positions. As the Third Circuit noted in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1066 (1980), the "striking similarity" between the products would make it unlikely that the brand-name manufacturer, if sued by an injured consumer of "look-alikes," could escape.[37]

The policies of state substitution laws thus parallel that of the Lanham Act: consumers should not be de-

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[33] Petitioners are plainly wrong in arguing that, when substitution is permissible, mislabeling cannot deprive the brand-name manufacturer of sales. Even in cases where substitution is legal, a patient may prefer the trademarked product. Mislabeling deprives him of the opportunity to make that choice.

[34] *E.g., FTC v. Algoma Lumber Co.*, 291 U.S. 67, 81 (1934); *Pep Boys—Manny, Moe & Jack, Inc. v. FTC*, 122 F.2d 158 (3d Cir. 1941).

[35] The effective patent life of innovative drug products is already diminished substantially by the length of the regulatory approval process. *See Hearings on S. 255 Before the Senate Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981).

[36] *Cf.* Posner, *The Rule of Reason and the Economic Approach: Reflections on the* Sylvania *Decision*, 45 U. Chi. L. Rev. 1, 6 (1977).

[37] An affidavit filed in *Biocraft Labs., Inc. v. Merck & Co.*, No 77-693 (D.N.J.), describes a product liability suit in which only a fortuitous handwritten notation by the pharmacist disclosed that a "look-alike" drug had been substituted for the defendant's product. Affidavit of Ronald S. Henshall (Jan. 6, 1981).

ceived. The decision below reinforces that policy, and should be affirmed.

IV. PETITIONERS ARE GUILITY OF CONTRIBUTORY TRADEMARK INFRINGEMENT.

A. The Use of "Look-Alike" Drugs As An Instrument of Infringement Is So Widespread That Petitioners Must Have Anticipated That Their Products Would Be So Used.

Petitioners deny that they either intended or anticipated that their "look-alike" drugs would be used as an instrument of trademark infringement, so as to make them liable as contributory infringers. The evidence in this record, however, particularly when read in light of comparable evidence adduced in every other contested "look-alike" case—including cases to which petitioners here were parties—demonstrates that mislabeling and illegal substitution of generic drugs for trademarked products is pervasive. The court below thus was clearly correct in concluding that petitioners must have anticipated that their products would be used in this way.

1. As noted above, respondent proved a total of 34 separate instances of infringement.[38] Given the difficulty

[38] Petitioners suggest that labeling generic cyclandelate as "Cyclospasmol 400 mg. (Rugby)," "Cyclospasmol Gen. (Spencer Mead)" or "Hylan: Cyclospasmol" does not constitute trademark infringement. We submit that these uses of the trademark do constitute infringement, as they clearly would confuse and tend to mislead the ordinary drug purchaser. *See Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190, 197 (9th Cir. 1953); *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs., Inc.*, 211 U.S.P.Q. 1163, 1181 (D.N.J. 1980). They give every appearance of an effort by the pharmacist to disguise the fact that a generic substitute for Cyclospasmol® is being dispensed, by using a misleading label. Pharmacists may not engage in a comparative use of respondent's mark that would "create a reasonable likelihood that purchasers will be confused as to the source, identity, or sponsorship" of petitioners' products. *Smith v. Chanel, Inc.*, 402 F.2d 562, 563 (9th Cir. 1968). And in any event, in three cases the pharmacists simply labeled the generic product as "Cyclospasmol." *See* Pl. Exs. 82T, R. 392-93; 82DDD, R. 393; 82HHH, R. 85, 377.

of obtaining evidence of this kind, as the court of appeals observed (Pet. App. 81a), this number of proven violations is substantial.[39]

2. The evidence of record in other cases further demonstrates that infringement via mislabeling and illegal substitution of generics is widespread.

—In *SK&F v. Premo*, *supra*, test shoppings for Dyazide ® in three cities showed an unlawful substitution rate of four percent. Surveys in other cities showed mislabeling of generic substitutes for Darvon ® in 15 percent of the cases, and for Librium ® in 23 percent.[40]

—In *A.H. Robins v. Medicine Chest*, *supra*, in which petitioner Inwood was a defendant, the court found that on "numerous occasions" the defendant pharmacies had misused plaintiff's trademark Dimetapp.® 206 U.S.P.Q. at 1018.[41]

—In *Boehringer v. Pharmadyne*, *supra*, in which petitioner Premo was a defendant, more than 25 percent of the generics dispensed (six out of 22) were labeled solely with plaintiff's trademark Persantine.® In at least eight additional instances, a misleading label was used. 211 U.S.P.Q. at 1181.[42]

—In *Hoffmann-La Roche v. Premo*, *supra*, out of 65 pharmacies suspected of mislabeling generic products as Librax,® 43 percent (28 out of 65) either mislabeled or

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[39] *Cf. David Sherman Corp. v. Heublein, Inc.*, 340 F.2d 377, 380-81 (8th Cir. 1965).

[40] *SK&F* Appendix at 130-31. *See* 625 F.2d at 1059. The study of Librium ® marketing also revealed an illegal substitution rate of 4%. The court of appeals found these surveys persuasive. *See id.*

[41] The plaintiff's evidence showed that, during a two-year period, two pharmacies in Missouri had received no prescriptions whatsoever calling for generic formulations of Dimetapp,® but that each pharmacy had dispensed at least 1,700 generic tablets, Tr. 422, all illegally. *See* 206 U.S.P.Q. at 1019.

[42] A witness in the case who had been involved in ten or eleven test shopping surveys for various drugs testified that the rate of illegal substitution was 10%. Tr. 607-08.

failed to write any indication of the manufacturer. 210 U.S.P.Q. at 380.

—In *Biocraft v. Merck, supra*, 73.9 percent of the generics substituted in a Florida survey were mislabeled with the plaintiff's trademark Elavil.® Slip op. at 24.[43]

3. The records of other cases still pending, or in which judgment was entered by consent, confirm the prevalence of unlawful substitution and mislabeling.

—In *American Home Products Corp. v. Premo Pharmaceutical Laboratories, Inc.*, Civil No. 81-575 (D.N.J.) (pending), the generic was mislabeled with plaintiff's trademark Equagesic® in 62 percent of the substitutions (16 out of 26). Half of the mislabeled prescriptions bore only the word "Equagesic"; the other half carried such terms as "Equagesic (Shein)," "Equagesic Arb (SM)" and "Equagesic Generic."[44]

—In *Merck & Co. v. Barr Laboratories, Inc.*, Civil No. 80-3791 (D.N.J.), *consent judgment entered*, March 23, 1981, 30 out of 55 substitutions involved mislabeling with plaintiff's trademark Elavil.® Fifteen prescriptions were labeled simply "Elavil" or "Elavil" plus the generic name (amitriptyline), and 15 others bore such labels as "Elavil 25mg. gEq URL," "Elavil/g-25 mg." and "Elavil 25 mg G."

—*Ives Laboratories, Inc. v. Bioline Laboratories*, Civil No. 81-914 (D.N.J.) (pending), concerns cyclandelate, the same drug at issue in this Court. An affidavit filed in that case identifies 40 percent of the substitutions (10 out of 25) as mislabeled. Sixteen percent (four out of 25) were labeled simply "Cyclospasmol" and the other

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[43] In *Smith Kline & French v. Heart Pharmaceutical, supra*, 90 F. Supp. at 977-78, there were 19 examples of passing off. In *Merrell-National Labs., Inc. v. Zenith Labs., Inc.*, 194 U.S.P.Q. 157, 158 (D.N.J. 1977), *denial of redetermination aff'd*, 579 F.2d 786 (3d Cir. 1978), there were nine instances. In *Smith Kline & French v. Broder, supra*, 125 U.S.P.Q. at 302, unlawful substitution took place "in many instances."

[44] Affidavit of Ferdinand Bovoso (Feb. 10, 1981).

24 percent (six out of 25) bore labels such as "Cyclospasmol 200 mg. Generic" and "Cyclospasmol-Gen 200 mg." [45]

Unlawful substitution and mislabeling are so widespread because they increase pharmacy profits. Petitioners argue that because many of the infringing sales in this case were at "the generic price," [46] the pharmacists obtained no financial benefit. But pharmacies' margins of profit usually are greater on sales of generic drugs than on sales of the trademarked products.[47] Furthermore, it is now well-recognized that pharmacists often fail to pass on to consumers anything like the full cost savings they themselves realize through substitution.[48] Indeed, "the generic price" in some pharmacies may be above that charged elsewhere for the original trademarked product.[49]

Given this economic temptation, and the large number of cases in which mislabeling and illegal substitution have been proved, it is disingenuous for petitioners to claim that they could not anticipate that the "look-alike" appearance of their products would encourage these practices. Such use of "look-alikes" is inevitable, and everyone familiar with the pharmaceutical industry knows it.[50]

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[45] Affidavit of Ferdinand Bovoso (June 18, 1981).

[46] There is, of course, no such thing as "the generic price." Different generic manufacturers charge different prices, just as do different pharmacists.

[47] *Drug Product Selection: Staff Report to the Federal Trade Commission* 94 (1979); *Smith Kline & French v. Broder*, *supra*, 125 U.S.P.Q. at 302.

[48] *E.g.*, N.Y. Att'y Gen. *et al.*, *Report on New York Generic Substitution Law*, March 13, 1979, at 17-18.

[49] *See* N.Y. Att'y Gen. *et al.*, *Report*, n.48 *supra*, at 14; S. Bitterman, "Generic Drug Law Gives Stores Windfall Profits," *Miami Herald*, Aug. 13, 1978, at 1A.

[50] Although the lawfulness of petitioners' conduct under Section 43(a) of the Lanham Act is not before the Court, the evidence in this case is the same as that on which other courts have found a Section 43(a) violation. Section 43(a), 15 U.S.C. § 1125(a), for-

B. The Ruling Below Is Consistent With *Sears* and *Compco*.

The decision of the court below is in no way inconsistent with *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), in which this Court held that federal patent law preempts the power of the states to prohibit the imitation of articles not protected by patents.

First, as four circuits have held, *Sears* and *Compco* have no bearing on cases under the Lanham Act, a federal statute.[51] *Second*, as between the two federal policies implicated in this case—the policy favoring competition and the policy against trademark infringement—there is no reason to subordinate one to the other.[52] Rather, the two

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bids false designations of origin and false descriptions and representations. Two separate violations of Section 43(a) have been made out in this case.

First, these manufacturers and distributors of "look-alike" products should reasonably have anticipated pharmacists' passing off the drugs as Cyclospasmol® and are contributorily liable under Section 43(a) for this misconduct. *SK&F v. Premo, supra*, 625 F.2d at 1062, 1065-66; *Hoffmann-La Roche v. Premo, supra*, 210 U.S.P.Q. at 386.

Second, petitioners are liable for unprivileged imitation. *See SK&F v. Premo, supra*, 625 F.2d at 1062-63, 1065-66. The "look-alike" appearance of petitioners' products is not functional, as it serves no purpose but the deception of patients. See pp. 9-20 *supra*. This deception stems from the fact that consumers identify respondent's trademarked product by its size, shape and color. See pp. 10-11 *supra*. This, as well as respondent's evidence of extensive sales and promotion, establishes "secondary meaning" for purposes of Section 43(a). *SK&F v. Premo, supra*, 625 F.2d at 1063-65; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1177-80.

[51] Pet. App. 47a-48a; *SK&F v. Premo, supra*, 625 F.2d at 1065-66; *Truck Equipment Serv. Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1214 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976); *Rolls-Royce Motors Ltd. v. A&A Fiberglass, Inc.*, 428 F. Supp. 689, 692 (N.D. Ga. 1976), *interpreting Boston Professional Hockey Ass'n, Inc. v. Dallas Cap & Emblem Mfg., Inc.*, 510 F.2d 1004 (5th Cir.), *cert. denied*, 423 U.S. 868 (1975).

[52] *See FCC v. RCA Communications, Inc.*, 346 U.S. 86, 92 (1953).

policies should be reconciled, as the Second Circuit has done. Copying is in some circumstances a permissible form of competition, but it is not a permissible device to facilitate trademark infringement.[53] No issue of trademark infringement was involved in *Sears* and *Compco*. Indeed, it was not even claimed in those cases that the imitations had in any way been palmed off or substituted for the original products. Deception of purchasers, which is the heart of this case, was not involved in *Sears* and *Compco* at all.[54]

Third, in the unique context of prescription drugs, the size, shape and color of the product constitute "trade dress," which *Sears* and *Compco* protect.[55] The Court plainly contemplated that there would be some means, such as trade dress or labeling, by which a manufacturer could identify his product and distinguish it from similar products made by others (376 U.S. at 232, 238). The method of distributing prescription drugs allows no opportunity for labeling or for any form of "trade dress" other than the size, shape and color of the product itself. The manufacturer's package, no matter how distinctive in appear-

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[53] *Cf. Standard Oil Co. (Kentucky) v. Humble Oil & Ref. Co.*, 363 F.2d 945, 954 (5th Cir. 1966), *cert. denied*, 385 U.S. 1007 (1967) ("The antitrust laws require competition, not piracy * * *. There is not now, nor has there ever been, a conflict between the antitrust laws and trademark laws or the law of unfair competition").

[54] In *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 487 (1974), the Court emphasized that nothing in *Sears* or *Compco* "requires that States refrain from action to prevent * * * [commercial conduct costly to] the basic decency of society," which surely includes deception of consumers. *A fortiori*, Congress is free to act.

[55] *SK&F v. Premo*, *supra*, 625 F.2d at 1064; *Biocraft v. Merck*, *supra*, slip op. at 2; *Boehringer v. Pharmadyne*, *supra*, 211 U.S.P.Q. at 1171-72, 1174, 1178, 1183; *Hoffmann-La Roche v. Premo*, *supra*, 210 U.S.P.Q. at 382-83. In the *Boehringer* case, Premo, a petitioner here, apparently treated the appearance of its "look-alike" product as "dress." *See* 211 U.S.P.Q. at 1182. Evidently this is also the view of the consumer groups supporting petitioners as *amici*. *See* Brief *Amici Curiae* of American Ass'n of Retired Persons and National Retired Teachers Ass'n, at 3, 4, 5.

ance or conspicuously labeled, never reaches the patient. As the district court found (Pet. App. 61a) and as petitioners' *amicus* supporter NAPM concedes (Br. at 7), any imprinting on the capsules themselves would be too small to be useful, particularly for those consumers—like most users of Cyclospasmol ® and other prescription drugs[56]—with "over-fifty" eyes. *SK&F v. Premo, supra*, 625 F.2d at 1061.[57] Nothing in *Sears* or *Compco*, therefore, renders the district courts impotent to grant effective relief under the Lanham Act against "look-alikes" as a form of consumer deception.[58]

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[56] Brief *Amici Curiae* of American Ass'n of Retired Persons and National Retired Teachers Ass'n, at 2-3 n.1.

[57] For this reason, as the Third Circuit held in *SK&F, supra*, no relief in "look-alike" cases short of an injunction against copying will suffice. Certainly mere exhortations on the manufacturers' bulk packages against illegal substitution and mislabeling would be ineffectual, as the district court found (Pet. App. 61a). Petitioners' reliance on *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938), and *William R. Warner Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), as precluding injunctions against copying is misplaced. In *Kellogg*, 97.5% of defendant's product reached consumers in distinctive packaging; no infringement of a registered trademark was established; the products were of different size, so that "no person familiar with plaintiff's product would be misled" (at 121); the shape in question was functional; and there was no evidence of passing off. Similarly, in *Warner* the chocolate that gave the product its color "serve[d] a substantial and desirable use" as a flavoring agent, "to say nothing of its effect as a suspending medium" (at 531), and thus was functional. None of this is true here.

[58] Petitioner Inwood's reliance on the First Amendment is a sham. Its advertising was not held unlawful by the court of appeals, but merely served as evidence of the Lanham Act violation: the manufacture and distribution of "look-alike" drugs with the intention or knowledge that they would be instruments of trademark infringement. The advertising simply provided additional evidence of petitioners' state of mind. The use of truthful speech to evidence a violation of law, by showing the defendant's state of mind, does not contravene the First Amendment. *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 n.3 (1965).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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January 4, 1982

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
Washington, D.C. 20201

Sep. 4, 1980

Mr. Milton A. Bass
General Counsel
Mr. George Schwartz
Executive Director
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017

Dear Messrs. Bass and Schwartz:

I have given careful consideration to the proposal presented in your letter of July 14 that the color, size and shape of a drug product be included as specifications in the approval of a new drug. Although I appreciate the basis for your concern, I do not believe that FDA should at this time attempt to resolve the drug product appearance issue as you propose.

As I understand the effect of your proposal, the specification of a drug product's color, size and shape in a new drug approval would link those characteristics of the drug to its generic identity. For a subsequent manufacturer to market a therapeutically equivalent product, it would, according to my understanding of the effect of your proposal, be required to duplicate the appearance of the original product.

However, I am unable to conclude that the appearance of drug products is closely enough related to their safety and effectiveness that the Agency can, on the basis of its present experience, require that generic drug products duplicate the appearance of their innovator drug counterparts. It has been the Agency's practice routinely

to approve new drug applications and abbreviated new drug applications for drug products that duplicate the color, size and shape of the innovator's product. But the Agency has not required that duplicate drug products have the same color, size and shape as the innovator product, and the Agency has not taken action affirmatively to encourage similarity in appearance between innovator products and their generic versions. As you know, there is presently controversy, including court litigation, associated with the appearance issue.

The Agency did support the Department of Justice's effort in one of those cases to promote the competitive position of less expensive generic drug products. *See Amicus* brief filed in *Smith Kline & French Company* v. *Premo Pharmaceutical Laboratories*, No. 79-2823 (3rd Cir. 1980) (copy enclosed). However, as we stated in our brief in the *Premo* case, we do not believe that the health and safety issues associated with the appearance of generic drug products prevent the competition and trademark issues from being resolved in this area as they would be in any other area. Rather, we believe that the manufacturers and distributors of drug products should be free to adopt whatever strategy they choose with respect to color, shape, and size as long as that strategy agrees with applicable law.

Thank you very much for your interest in this matter.

Sincerely yours,

/s/ Jere E. Goyan
JERE E. GOYAN
Commissioner of Food and Drugs

Enclosure